



GUIDANCE DOCUMENT FOR REQUEST FOR EXEMPTION OF SELECT BIOLOGICAL AGENTS AND TOXINS



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select biological agents and toxins were published by HHS (42 CFR 73; December 13, 2002) and by USDA (9 CFR 121 and 7 CFR 331; December 13, 2002).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities or facilities in complying with this legal obligation.

This form should be used to apply for exemption from the requirements of 42 CFR 73, 9 CFR 121, or 7 CFR 331 in cases of: (a) Use of an investigational product, or, (b) Due to public health or agricultural emergency. This exemption request should be sent to either CDC or APHIS, as appropriate, for exemption consideration. For HHS agents and toxins, the applicant should contact CDC (telephone: 404-498-2255; facsimile: 404-498-2265). For USDA agents and toxins, the applicant should contact APHIS (for animal agents and toxins telephone: 301-734-3277; facsimile: 301-734-3652). For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC at the numbers above. For plant agents and toxins the applicant should contact APHIS (telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>.

INSTRUCTIONS

Entities/facilities may apply for an exemption from the requirements of 42 CFR 73, 9 CFR 121, or 7 CFR 331 using this form (1) If the entity/facility possesses, uses, or transfers investigational or experimental products that are, bear, or contain select biological agents or toxins; or (2) In order to respond to a domestic or foreign public health or agricultural emergency.

All applicants must complete Section 1. Section 2 should be completed for those entities or facilities that wish to request an exemption due to investigational use of select biological agents or toxins. Section 3 should be completed for those entities or facilities that wish to apply for an exemption due to a public health or agricultural emergency. Applicants must sign and date the form.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-3277. This guidance document and form are also available at <http://www.cdc.gov/od/sap>, <http://www.aphis.usda.gov/vs/ncie/bta.html> and <http://www.aphis.usda.gov/ppq/permits>.

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA animal agents and toxins, return completed forms to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231.

For HHS/USDA overlap select agents, return forms to: either CDC or APHIS at the addresses provided.

For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236

SECTION 1 – TO BE COMPLETED BY ALL APPLICANTS					
Entity/Facility name			Entity registration number (if applicable) APHIS# CDC#		
Entity/Facility address (NOT a post office address)			City	State	Zip code
Applicant		Title	Telephone	FAX	E-mail
Address (NOT a post office address)			City	State	Zip Code
Are you the: <input type="checkbox"/> Laboratory Director <input type="checkbox"/> Other (specify): <input type="checkbox"/> Responsible Official					
SECTION 2 – TO BE COMPLETED FOR INVESTIGATIONAL/ EXPERIMENTAL PRODUCT EXEMPTION					
FDA IND number	FDA product name		This product has been approved for Phase I clinical trials by FDA: <input type="checkbox"/> Yes <input type="checkbox"/> No		
USDA veterinarian product code number	USDA veterinarian product name		This product has been tested and approved for field trials by USDA: <input type="checkbox"/> Yes <input type="checkbox"/> No		
Investigational/ Experimental product (Give select agent name and characterization)					
Federal act that authorizes investigational use of this product					
Provide a detailed justification for exemption from registration for select biological agents and toxins due to investigational use. Provide sufficient detail to argue that applying additional regulation under 42 CFR 73, 9 CFR 121, or 7 CFR 331 (as applicable) would not be necessary to protect public health and safety (attach additional sheets if necessary):					
SECTION 3 – TO BE COMPLETED FOR PUBLIC HEALTH OR AGRICULTURAL EMERGENCY EXEMPTION					
INFORMATION ON PUBLIC HEALTH OR AGRICULTURAL EMERGENCY					
Name of person most familiar with public health or agricultural emergency				Telephone number	
Description of select agent(s) involved in public health or agricultural emergency					
Description of disease caused by select agent(s):					

Date of first confirmed cases	Number of cases biweekly	How diagnosis was made
Laboratory that confirmed original diagnosis	Name, address and phone of laboratory director	
Describe circumstances of public health/ agricultural emergency (attach additional sheets if necessary):		
INFORMATION ON SELECT BIOLOGICAL AGENTS AND TOXINS INVOLVED		
Location where work with specimens will be conducted:	Building:	Room:
Biosafety level of laboratory	Name of laboratory supervisor	
Type of specimens that will be received: <input type="checkbox"/> Clinical/diagnostic (Specify from which species): _____ <input type="checkbox"/> Isolates (Specify how and when they will be characterized): _____ <input type="checkbox"/> Environmental (Specify): _____ <input type="checkbox"/> Other (Specify): _____		
Is this source expected to provide additional specimens? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Anticipated quantity of specimens to be received:		
Anticipated time period to receive specimen (give estimated end date):		

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121 or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Applicant: _____ Typed or printed name of Applicant: _____

Title of Applicant: _____ Date: _____

Public reporting burden: Public reporting burden of this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).